



[EPA-HQ-ORD-2013-0292; FRL-9807-5]

Request for Information and Citations on Methods for Cumulative Risk Assessment

AGENCY: Office of the Science Advisor, Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The United States Environmental Protection Agency (EPA) is requesting information and citations on approaches and methods for the planning, analysis, assessment, and characterization of cumulative risks to human populations and the environment. The EPA is developing guidelines for the assessment of cumulative risk as defined and characterized in the EPA 2003 publication *Framework for Cumulative Risk Assessment*, “An analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors” using scientifically defensible approaches and methods. The Guidelines will assist agency programs and regions in the assessment of risk and in decision making, including the planning and development of regulations and permits. This notice solicits information and citations pertaining to approaches and methods that can be used to plan and conduct cumulative risk assessments (CRA). Published background information regarding cumulative risk can be found at http://www.epa.gov/raf/publications/pdfs/frmwrk_cum_risk_assmnt.pdf or from the person listed under **FOR FURTHER INFORMATION CONTACT**.

DATES: Information and citations may be submitted on or before Friday, June 28, 2013.

ADDRESSES: Submit your information, identified by Docket ID No. [EPA-HQ-ORD-2013-0292](http://www.epa.gov/raf/publications/pdfs/frmwrk_cum_risk_assmnt.pdf), by one of the following methods:

Internet: <http://www.regulations.gov>: Follow the website instructions for submitting information.

Email: ORD.Docket@epa.gov.

Mail: Environmental Protection Agency, EPA Docket Center EPA/DC, ORD Docket, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

Hand Delivery: The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue, NW, Washington, DC 20460. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202)566-1744 or email the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available online at <http://www.epa.gov/epahome/dockets.htm>.

Instructions: Direct your information and citations to Docket ID No. [EPA-HQ-ORD-2013-0292](#). The Agency's policy is that all submissions received will be included in the public docket without change and will be made available online at <http://www.regulations.gov>, including any personal information provided, unless the information includes data claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> website is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your submission to the docket. If you send an email with information directly to the EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the information that is placed in the public docket and made available on the Internet. If you submit information electronically, the EPA recommends that you include your name and other contact information in the body of your submission and with any disk or CD-ROM you submit. If the EPA cannot read your information due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your information. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Any members of the public who wish to receive further information about submitting information on methods for cumulative risk assessment should contact Lawrence Martin at telephone number (202)564-6497 or email address

martin.lawrence@epa.gov, mailing address Environmental Protection Agency, Office of the Science Advisor, Mail Code 8105R, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

A. Does this information request apply to me?

The purpose of the CRA Guidelines is to delineate CRA methods that will support informed decision-making at EPA. This request also may be of interest to persons involved with the design, formulation, and conduct of risk assessments more generally. Since many and various entities may also be interested, the EPA has not attempted to describe all the specific entities that may be interested in this request. If you have any questions regarding the applicability of this request, please consult Lawrence Martin listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I access electronic copies of this document and other related information?

You may use <http://www.regulations.gov>, or you may access this *Federal Register* document via the EPA's internet site under the "*Federal Register*" listings at <http://www.epa.gov/fedrgstr>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the ORD Docket, EPA/DC Public Reading Room. The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue, NW, Washington, DC 20460; its hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays.

Please call (202)566-1744, or email the ORD Docket at ord.docket@epa.gov for instructions. Updates regarding the Public Reading Room access are available at <http://www.epa.gov/epahome/dockets.htm>.

C. What should I consider as I prepare my information for the EPA?

You may find the following suggestions helpful for preparing your information:

1. Explain the information you are providing as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies or citations for any technical information and/or data used that support the information you provide. Methods published in the peer-reviewed literature are preferred and are more readily useful.
4. Provide specific examples.
5. To ensure proper receipt by the EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and *Federal Register* citation.

Responses to this request are voluntary. This notice does not obligate the U.S. Government to award a contract or otherwise pay for the information provided in response to this request. The U.S. Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Respondents are advised that the U.S. Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted.

D. Background

Former EPA Administrator Carol Browner transmitted the EPA Science Policy Council's *Guidance on Cumulative Risk Assessment, Part 1, Planning and Scoping* in a memo dated July 3, 1997. Administrator Browner wrote: "Today, we are providing guidance for all EPA offices on cumulative risk assessment. This guidance directs each office to take into account cumulative risk issues in scoping and planning

major risk assessments and to consider a broader scope that integrates multiple sources, effects, pathways, stressors and populations for cumulative risk analyses in all cases for which relevant data are available. This assures a more consistent and scientifically complete Agency-wide approach to cumulative risk assessments in order to better protect public health and the environment.” Subsequently, the EPA Risk Assessment Forum was charged to complete comprehensive guidelines for the assessment of cumulative risks. In May 2003, the RAF released the *Framework for Cumulative Risk Assessment* (EPA/630/P-02/001F), available to download from the internet at http://www.epa.gov/raf/publications/pdfs/frmwrk_cum_risk_assmnt.pdf. The 2003 CRA Framework was the EPA’s first step toward development of the CRA Guidelines. The foreword to the Framework notes that the National Research Council (NRC) (http://www.nap.edu/catalog.php?record_id=2125#toc) and the Presidential-Congressional Commission on Risk Assessment (http://www.riskworld.com/Nreports/1996/risk_rpt/Rr6me001.htm) assign importance to understanding risk from multiple stressors, and that EPA had begun to address approaches to CRA. The NRC and EPA’s Science Advisory Board have provided consistent recommendations that encourage better integrated, multi-stressor approaches to understanding risks to human health and the environment. For example, in *Science & Decisions* 2009, the NRC recommends that EPA develop CRA tools (see pg. 236). “EPA is increasingly asked to address broader public-health and environmental-health questions involving multiple exposures, complex mixtures, and vulnerability of exposed populations – issues that stakeholder groups... often consider to be inadequately captured by current risk assessments. There is a need for cumulative risk assessments...” (*Science and Decisions*; available to download from the internet at http://www.nap.edu/catalog.php?record_id=12209).

E. Request for Information and Citations on Cumulative Risk Assessment Methods

To date, CRA experience at EPA has been principally in the application of CRA screening and chemical additivity methods for aggregating risk from multiple exposures and/or toxicity pathways. These have been conducted by EPA programs and regions. This limited application of CRA has substantiated the value of multi-chemical/stressor assessments in an environmental risk assessment context, but illustrates a more limited application than that recommended by the NRC, or discussed in the 2003 CRA Framework. EPA requests information on and citations for CRA methods that have been employed to date and approaches that could assist EPA in the development of improved CRA methods. Methods and information published in the peer-reviewed literature are preferred and would be more readily useful. Information and citations are also being requested for existing, on-going cumulative risk assessments that incorporate the assessment of multiple chemical or non-chemical stressors, and that address any of the following characteristics: multi-stressor, multi-media, multi-receptor, including assessment of a vulnerable population, both human and environmental health considerations, or socio-economic stressors. EPA also requests information on examples where CRA has been successfully used for decision making at the local, state, national, or international levels, including a description of the circumstances leading to the use of CRA methods in those examples.

More specifically, information and citations are sought for the following purposes:

1. Methods for CRA planning, scoping and problem formulation to ensure that the scope of a CRA is tractable and also adequately addresses the key concerns of a specified environmental problem. This includes methods that could be used for the following: evaluating population vulnerabilities that are either perceived or empirically demonstrated as important elements of a CRA; involving the spectrum of interested/affected parties in formulating the problem for assessment or decision; considering stakeholder objectives and integrating them into an analysis; identifying the most influential stressors that need to be considered in a CRA; and developing conceptual models that link stressors and health outcomes.

2. Methods to identify and quantify population vulnerabilities (risk factors) and buffers (protective factors) that may influence exposures, dose-response or risk/hazard posed by environmental contaminant exposures, and methods to integrate population vulnerabilities and buffers into a CRA. Vulnerabilities could include factors leading to differential exposures, differential responses, preparedness and resiliency within a population.
3. Methods for integrating chemical, physical, biological and socio-economic stressors within a CRA, including quantifying and integrating “exposure” and “dose-response” for disparate stressors, and grouping of chemical and nonchemical stressors for combined (or integrated) risk analysis.
4. Methods for characterizing integrated risks posed by disparate stressors in a CRA context. These could include methods and/or study data from epidemiology, toxicology, ecology, health economics, chemical mixtures risk assessment, social sciences, dose response modeling and statistics (among others); and may also include addressing spatial and temporal scales.
5. Methods to integrate ecological and human health exposures and health effects in a CRA.
6. Approaches for addressing stakeholder participation, engagement and risk communication when conducting a CRA.

Date: April 22, 2013.

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